

TRAUMEEL RX- aconitum napellus, arnica montana root, atropa belladonna, bellis perennis, calendula officinalis flowering top, matricaria recutita, echinacea, unspecified, echinacea purpurea, hamamelis virginiana root bark/stem bark, calcium sulfide, hypericum perforatum, mercurius solubilis, achillea millefolium and comfrey root ointment
Biologische Heilmittel Heel

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Traumeel Ointment RX

ACTIVE INGREDIENTS

Active ingredients: Each 100 g contains:

*Aconitum napellus 1X 0.050g; *Arnica montana, radix 3X 1.50g; *Belladonna 1X 0.050g; *Bellis perennis MT 0.100g; *Calendula officinalis MT 0.450g; *Chamomilla MT 0.150g; *Echinacea MT 0.150g; *Echinacea purpurea MT 0.150g; *Hamamelis virginiana MT 0.450g; Hepar sulphuris calcareum 6X 0.025g; *Hypericum perforatum 6X 0.090g; Mercurius solubilis 6X 0.040g; *Millefolium MT 0.090g; *Symphytum officinale 4X 0.100g.

***Natural Ingredients**

PURPOSE

Analgesic & Anti-inflammatory

KEEP OUT OF REACH OF CHILDREN

Keep out of Reach of Children

INDICATIONS AND USAGE

Indications:

Traumeel ointment is an analgesic/antiflammatory homeopathic drug product indicated for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

WARNINGS

Warnings:

For external use only. Cetylstearyl alcohol may cause local skin reactions, i.e. contact dermatitis. Do not apply over large areas of the body. Do not apply over open wounds or broken skin. If symptoms persist or worsen, or if a rash develops, a physician should be consulted.

DOSAGE AND ADMINISTRATION

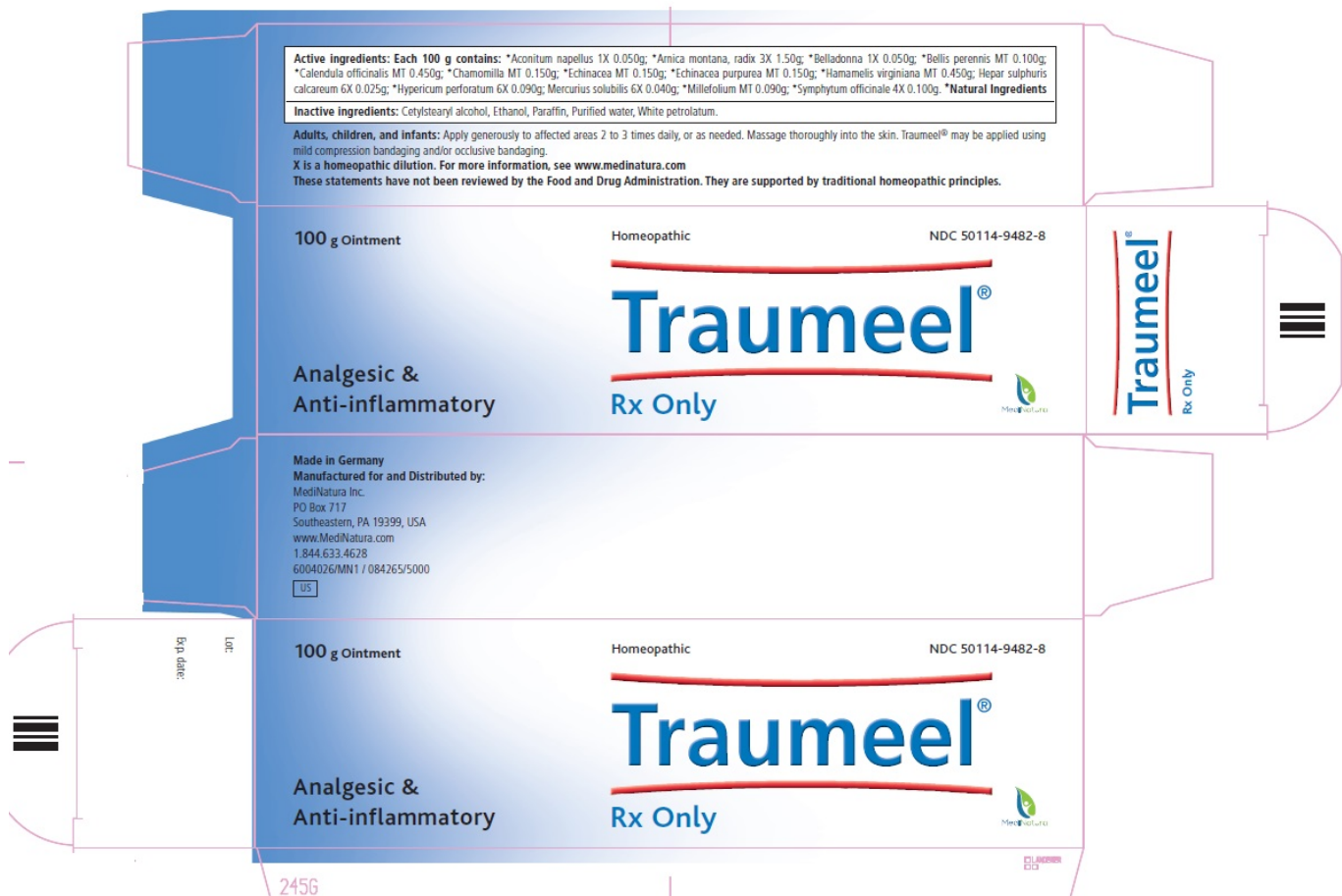
Standard Dosage:

Adults, children and infants: Apply generously to affected areas 2 to 3 times daily, or as needed. Rub gently into the skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging.

INACTIVE INGREDIENTS

Inactive ingredients:

Paraffin, liquid, Cetostearyl alcohol (type A), emulsifying, Paraffin, white soft, Ethanol (96 per cent)



TRAUMEEL RX

aconitum napellus, arnica montana root, atropa belladonna, bellis perennis, calendula officinalis flowering top, matricaria recutita, echinacea, unspecified, echinacea purpurea, hamamelis virginiana root bark/stem bark, calcium sulfide, hypericum perforatum, mercurius solubilis, achillea millefolium and comfrey root ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51885-9482
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	1 [hp_X] in 1 g
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	3 [hp_X] in 1 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	1 [hp_X] in 1 g

BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 1 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 g
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	1 [hp_X] in 1 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	1 [hp_X] in 1 g
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [hp_X] in 1 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	1 [hp_X] in 1 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 g
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 1 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	4 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51885-9482-8	1 in 1 CARTON	04/28/2016	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51885-9482-6	4 g in 1 TUBE; Type 0: Not a Combination Product	04/28/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/28/2016	

Labeler - Biologische Heilmittel Heel (315635359)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(51885-9482)

